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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/732,350

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Allan Svendsen

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EXAMINER

PAK, YONG D

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/732,350	Applicant(s) SVENDSEN ET AL.	
	Examiner Yong D. Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-70 and 72-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-70 and 72-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/032,315.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/16/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a divisional of 09/396,260, now issued as US Patent 6,184,015, which is a divisional of 09/032,315, now issued as US Patent 5,985,818.

The amendment filed on February 8, 2008, amending claims 64 and 78 and canceling claim 71, has been entered.

Claims 64-70 and 72-95 are pending and are under consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 16, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

Applicant's amendment and arguments filed on February 8, 2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 101

In view of the amendment of claims 64 and 78, the rejection of claims 64-70, 73-76 and 78-94 under 35 U.S.C. 101, as being drawn to non-statutory subject matter has been **withdrawn**.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64-70 and 72-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a variant of a laccase having the amino acid sequence of SEQ ID NO:10, wherein the variant has laccase activity and comprises one or more amino acid mutations at amino acid positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the limitation of comprising mutations at positions corresponding to 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10 provide no description on the structure of other parts of the variant laccase because the claimed variant is not limited to only those mutations at positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10. Therefore, while the variant comprises the recited mutations, the same variant comprises any amino acids in any other positions. Therefore, Examiner has interpreted

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the claims broadly to encompass variants of SEQ ID NO:10, wherein the variant comprises one or more amino acid mutation at amino acid positions corresponding to 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10 and one or more amino acid mutations at any other amino acid positions. Therefore, the claims encompass laccase having any structure.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, (or) chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The recitation of “laccase” fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus without providing any definition of the structural features of the species within the genus. The CAFC in *UC California v. Eli Lilly*, (43 USPQ2d 1398) stated that: “in claims to genetic material, however a generic statement such as ‘vertebrate insulin cDNA’ or ‘mammalian insulin cDNA,’ without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.” Similarly with the claimed genus of polypeptides having “laccase” activity the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus.

The claims are drawn to variant laccase having any structure. The specification only describes one representative species, specific laccase variants of a single laccase having the amino acid sequence of SEQ ID NO:10, wherein the variant laccase consists of substitutions at positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10 and having laccase activity. While MPEP 2163 acknowledges that in certain situations “one species adequately

supports a genus," it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." In view of the widely variant species encompassed by the genus, a few mutants of the laccase of SEQ ID NO:10 are not enough and does not constitute a representative number of species to describe the whole genus of any or all variants of SEQ ID NO:10 and there is no evidence on the record of the above mentioned few mutants of SEQ ID NO:10 and the structure of any or all variants of SEQ ID NO:10. Therefore, the specification fails to describe a representative species of the genus comprising any or all variants having any structure.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 64-70 and 72-95.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants should note that the rejection has been amended in light of the amendment of the claims.

Applicants argue that since (1) the specification describes a number of positions and mutations that could be altered in SEQ ID NO:10 and therefore disclosures a

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representative number of species within the scope of the genus and (2) the level of skill in the art of enzyme variants is high, the claims meet the written description requirement. Examiner respectfully disagrees. The claims are not limited to specific mutations at positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10. While the variant comprises the recited mutations, the same variant comprises any amino acids in any other positions. Therefore, the claims encompass a genus of variants of SEQ ID NO:10, wherein the variant comprises one or more amino acid mutation at amino acid positions corresponding to 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10 and one or more amino acid mutations at any other amino acid positions. The genus comprising any or all recombinants, variants and mutants of SEQ ID NO:10 does not possess any common attributes other than having the recited activity and the above 1 to 28 amino acids. Therefore, the specification lacks description of a representative number of species to describe the whole genus. As discussed in the written description guidelines, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are

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adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only a few species within the genus. In the instant case the claimed genera of the claims includes species which are widely variant in structure. The claims are drawn to structurally diverse species as it encompasses any or all mutants of SEQ ID NO:10. As such, the description of solely functional features present in all members of the genus is insufficient to be representative of the attributes and features of the entire genus.

Hence the rejection is **maintained**.

Claims 64-70 and 72-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for variants of a laccase having the amino acid sequence of SEQ ID NO:10, wherein the variant laccase consists of substitutions at positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10 and having laccase activity, does not reasonably provide enablement for variants laccase having any structure. The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a variant of a laccase having the amino acid sequence of SEQ ID NO:10, wherein the variant has laccase activity and comprises one or more amino acid mutations at amino acid positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514.

The breadth of the claims.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the limitation of comprising mutations at positions corresponding to 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10 provide no description on the structure of other parts of the variant laccase because the claimed variant is not limited to only those mutations at positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514. Therefore, while the variant comprises the recited mutations, the same variant comprises any

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amino acids in any other positions. Therefore, Examiner has interpreted the claims broadly to encompass variants of SEQ ID NO:10, wherein the variant comprises one or more amino acid mutation at amino acid positions corresponding to 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10 and one or more amino acid mutations at any other amino acid positions. Therefore, the claims encompass laccase having any structure.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides of virtually any structure. In the instant case, the specification only enables variants of a laccase having the amino acid sequence of SEQ ID NO:10, wherein the variant laccase consists of substitutions at positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 or 514 and/of SEQ ID NO:10 and having laccase activity.

The quantity of experimentation required to practice the claimed invention based on the teachings of the specification.

While enzyme isolation techniques, recombinant and mutagenesis techniques were known in the art at the time of the invention, e.g. mutagenesis, and it is routine in the art to screen for variants comprising multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art

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would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

In the absence of: (a) rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function, (b) a correlation between structure and function of laccase activity, the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. One of skill in the art would have to test these infinite possible polypeptides to determine (1) which mutants have laccase activity, (2) the specific substrates targeted by such proteins and (3) how to use those polypeptides not having laccase activity. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, as is the case herein, the specification must provide a reasonable amount of guidance which respect to the direction in which the experimentation should proceed so that a reasonable number of species can be selected for testing. In view of the fact that such guidance has not been provided in the instant specification, it would require undue experimentation to enable the full scope of the claims

The state of prior art, the relative skill of those in the art, and predictability or unpredictability of the art.

Since the amino acid sequence of the mutant determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant

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of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. In the instant case, neither the specification or the art provide a correlation between structure and activity such that one of skill in the art can envision the structure of any polypeptides having the same biological function as that of the polypeptide of SEQ ID NO:10 or predict the function of a polypeptide from its primary structure. In addition, the art does not provide any teaching or guidance as to (1) which amino acids within the polypeptides of SEQ ID NO:10 (other than the amino acid at positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 or 514) can be modified and which ones are conserved such that one of skill in the art can make the recited polypeptides having the same biological activity as that of the polypeptide of SEQ ID NO:10, (2) which segments of the polypeptide of SEQ ID NO:10 are essential for activity, and (3) the general tolerance of laccase to structural modifications and the extent of such tolerance. The art clearly teaches that changes in a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are required for that activity is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. For example, Branden et al. (introduction to Protein Structure, Garland Publishing Inc., New York, page 247, 1991 –cited previously on form PTO-892) teach that (1) protein engineers are frequently surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in

enzymes, (2) the often surprising results obtained by experiments where single mutations are made reveal how little is known about the rules of protein stability, and (3) the difficulties in designing de novo stable proteins with specific functions.

The amount of direction or guidance presented and the existence of working examples.

The specification only enables variants of a laccase having the amino acid sequence of SEQ ID NO:10, wherein the variant laccase consists of substitutions at positions 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 or 514 of SEQ ID NO:10 and having laccase activity. However, the specification fails to provide any information as to (1) specific substrates associated with the laccase of SEQ ID NO:10 (2) structural elements required in a polypeptide having laccase activity, or (3) which are the structural elements in the polypeptide of SEQ ID NO:10 that are essential to display laccase activity. No correlation between structure and function of having laccase activity has been presented. There is no information or guidance as to which amino acid residues in the polypeptides of SEQ ID NO: 10 can be modified and which ones are to be conserved to create a polypeptide displaying the same activity as that of the polypeptides of SEQ ID NO:10.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability of the prior art in regard to structural changes and their effect on function and the lack of knowledge about a correlation between structure and function, an undue experimentation would be necessary one having ordinary skill in the art to make and

use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics recited in the claims are unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office Action, applicants have traversed the above rejection. Applicants should note that the rejection has been amended in light of the amendment of the claims.

Applicants argue that since each of the independent claims have been amended to recite “the amino acid sequence of SEQ ID NO:10, the claims are fully enabled. Examiner respectfully disagrees. Contrary to applicant’s statement that the Examiner “has indicated on the record that the claims are enable for variants of a laccase “having the amino acid sequence of SEQ ID NO:10”... See page 7’, the Office Action on page 7 states that variants of a laccase having the amino acid sequence of SEQ ID NO:, wherein the variant laccase consists of substitutions at positions..... of SEQ ID NO:10 and having laccase activity is enabling. Since the claims encompass variants of SEQ ID NO:10, wherein the variant comprises one or more amino acid mutation at amino acid positions corresponding to 93, 95, 106, 108, 109, 185-194, 234-236, 269, 293-294, 428, 433, 500, 506, 510, 511 and/or 514 of SEQ ID NO:10 and one or more amino acid mutations at any other amino acid positions, enable is lacking. As discussed above,

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predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a specific knowledge of and guidance with regard to which specific amino acids in the protein's sequence, can be modified such that the modified polypeptide continues to have said claimed activity. It is this specific guidance that applicants do not provide. While the art may teach in general the structure of laccase conserved amino acid sequences, x-ray crystal structure and etc, such teachings will not reduce the burden of undue experimentation on those of ordinary skill in the art.

Hence the rejection is **maintained**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 64 and 68 remain rejected under 35 U.S.C. 102(b) as being anticipated
by
Germann et al.

Claims 64 and 68 are drawn to a variant of a laccase having the amino acid sequence of SEQ ID NO:10, wherein said variant has an A108V mutation.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." While the variant comprises the recited mutation, a valine at position 108, the same variant comprises any amino acids in any other positions

Germann et al. (Proc. Natl. Acad. Sci (1986) 83: 8854-8858 – cited previously on form PTO-1892) discloses a laccase. The laccase of Germann et al. does not have an alanine at amino acid position corresponding to 108 of SEQ ID NO:10, but has a valine residue. Since (1) there is no limitation on the structure of the variant having laccase activity except comprising a valine at position 108 and (2) the instant claims are drawn to a product, which may be produced by the recited modification/starting material or not, Examiner takes the position that the laccase of Germann et al. reads on the instant claims. Whether the claimed product is obtained from the laccase of SEQ ID NO:10 or obtained from any source, as long as the resulting product has the structural limitations recited in the claims, the product is still the same and is within the scope of the claimed invention. Therefore, the reference of Germann et al. anticipates claims 64 and 68.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants should note that the rejection has been amended in light of the amendment of the claims.

Applicants argue that due to the amendment of the independent claim 64, the claims are no longer anticipated by Germann et al. Examiner respectfully disagrees.

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The limitation of comprising a mutation at positions corresponding to 108 of SEQ ID NO:10 provides no description on the structure of other parts of the variant laccase because the claimed variant is not limited to only the mutation at 108. Therefore, while the variant comprises the recited mutation, the same variant comprises any amino acids in any other positions. Since (1) there is no limitation on the structure of the variant having laccase activity except having a valine residue at position 108 and (2) the instant claims are drawn to a product, which may be produced by the recited modification/starting material or not, Examiner takes the position that the laccase of Germann et al. reads on the instant claims. Therefore, whether the claimed product is obtained from the laccase of SEQ ID NO:10 or obtained from any source, as long as the resulting product has the structural limitations recited in the claims, the product is still the same and is within the scope of the claimed invention.

Hence the rejection is maintained.

Claims 78, 80, 82, 84, 86 and 88 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fernandez-Larrea et al.

Claims 78, 80, 82, 84, 86 and 88 are drawn to a variant of a laccase having the amino acid sequence of SEQ ID NO:10, wherein said variant has mutations at positions 186, 188, 190, 192 and 194.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the claims have been construed as meaning a variant of a laccase of SEQ ID NO:10, wherein the

variant does not have residues L, K, S, A, F and N at positions 186, 188, 190, 192 and 194 of SEQ ID NO:10, respectively.

Fernandez-Larrea et al. (Mol Gen Genet. 1996 Oct 16;252(5):539-51 – cited previously on form PTO-892) discloses a laccase. The laccase of Fernandez-Larrea et al. does not have residues L, K, S, A, F and N at positions 186, 188, 190, 192 and 194 of SEQ ID NO:10, respectively. Since (1) there is no limitation on the structure of the variant having laccase activity except not having residues L, K, S, A, F and N at positions 186, 188, 190, 192 and 194 and (2) the instant claims are drawn to a product, which may be produced by the recited modification/starting material or not, Examiner takes the position that the laccase of Fernandez-Larrea et al. reads on the instant claims. Therefore, whether the claimed product is obtained from the laccase of SEQ ID NO:10 or obtained from any source, as long as the resulting product has the structural limitations recited in the claims, the product is still the same and is within the scope of the claimed invention. Therefore, the reference of Fernandez-Larrea et al. anticipates claims 78, 80, 82, 84, 86 and 88.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants should note that the rejection has been amended in light of the amendment of the claims.

Applicants argue that due to the amendment of the independent claim 78, the claims are no longer anticipated by Fernandez-Larrea et al. Examiner respectfully disagrees. The claims are drawn to a variant of a laccase of SEQ ID NO:10, wherein the variant does not have residues L, K, S, A, F and N at positions 186, 188, 190, 192

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and 194 of SEQ ID NO:10, respectively. The laccase of Fernandez-Larrea et al. does not have residues L, K, S, A, F and N at positions 186, 188, 190, 192 and 194 of SEQ ID NO:10, respectively. Since (1) there is no limitation on the structure of the variant having laccase activity except not having residues L, K, S, A, F and N at positions 186, 188, 190, 192 and 194 and (2) the instant claims are drawn to a product, which may be produced by the recited modification/starting material or not, Examiner takes the position that the laccase of Fernandez-Larrea et al. reads on the instant claims.

Hence the rejection is **maintained**.

In view of the amendment of claim 64 and cancellation of claim 71, the rejections under 102(b) and 102(e) as being anticipated by Pedersen et al. (US Patent 5,925,554, US Patent 6,140,092 and US Patent 5,998,353) have been **withdrawn**.

Conclusion

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/
Primary Examiner, Art Unit 1652